Remarks

This application has been carefully reviewed in light of the Office Action dated March 30, 2011, and subsequent Advisory Action dated June 21, 2011. Claims 1-3, 5-16, 21, 22, 25, 26, 28-30, 36, 43-52, 54, and 55 are currently in the application, with claims 1-3, 5-15, 29 and 36 having been withdrawn from consideration. Claim 16 is the independent claim currently under consideration. Claims 18-20, 23, 24, 31-35, 37-42, and 53 are cancelled herein without prejudice or disclaimer of the subject matter therein. Claims 16, 21, 22, 25, 26, 28, 30, 43-52, 54, and 55 have been amended herein. Support for the amendment is found in the original disclosure, including, for example, original paragraphs [0046], [0048] and original Figures 2-4. No new matter is believed to be added herein. Reconsideration and further examination are respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 16, 18-20, 23, 24, 26, 28, 31, 35, and 40-55 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,552,751 ("Inaba"). Claims 18-20, 23, 24, 31, 35, 40-42, and 53 have been cancelled, thereby rendering the rejection of these claims moot. As for the remaining claims, Applicant respectfully submits that the pending claims are patentably distinguishable over the applied reference for at least the following reasons.

A rejection under 35 U.S.C. § 102 in view of a prior art reference can be properly sustained only if every limitation in the claim is found in the reference, either explicitly or inherently. *See MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). This Inaba fails to do.

Amended independent claim 16 is directed to a discrete **single layer** cured film dosage to be taken orally, internally, or epidermally and having a **concentration gradient** of at least one

active ingredient. The film dosage is produced by forming a non-gelatin polymeric film with or without active ingredients incorporated therein and applying a polar liquid carrier to **one surface of the polymeric film**, the polar liquid carrier incorporating the at least one active ingredient. The applied polar liquid carrier is allowed to associate and cure with the polymeric film to result in the complete absorption of the at least one active ingredient within the polymeric film, thereby forming a single layer cured film dosage having a **concentration gradient within the film dosage**, from a first concentration of the active ingredient at a first side of the film dosage, to a second concentration of the active ingredient at a second side of the film dosage, the second side being opposite the first side, and the first concentration being greater than the second concentration. The processes described in Inaba do not produce a discrete single layer cured film dosage having a concentration gradient of at least one active ingredient as is produced by the steps recited in claim 16.

The Advisory Action states that Inaba "discloses a **multilayer dosage film** wherein drug layers are present within non-gelatin inactive polymeric layers." Advisory Action, p. 2. Inaba discloses that drug storing layers (2) or (3) are disposed between drug release controlling layers (1). Inaba, FIG. 1. The multi-layer film comprises **at least two** drug release controlling layers (1). Inaba, Col. 2: lines 4-11 and lines 51-60. The release rate of the drug is controlled by either changing the chemical (e.g., rate of dissolution) or physical (e.g., thickness) properties of the drug release controlling layers (1) or changing the number of drug release controlling layers (1) present in a given multi-layer film. *See* Inaba, Col. 3: lines 4-23. Accordingly, Inaba requires that the drug storing layers (2), (3) and the drug release controlling layers (1) **maintain their intercalated and separate relationship**. Otherwise, the drug release-control method taught by Inaba would be defeated. In addition, Inaba discloses that two or more drugs having different

pharmacological properties may be contained **in separate drug storing layers**. Inaba, Col. 3: lines 54-67. Accordingly, the drug storing layers (2) (3) and the drug release controlling layers (1) in all embodiments disclosed by Inaba **do not form a single layer cured film** as recited in claim 16.

Furthermore, nowhere does Inaba disclose controlling drug release by creating a concentration gradient of an active ingredient from "a first concentration of the active ingredient at [a] first side [of a non-gelatin polymeric film], to a second concentration of the active ingredient at a second side of the film," as recited in amended claim 16. Nor does Inaba disclose or suggest that the drug storing layers (2) or (3) of Inaba, which are not disposed at an exterior surface of Inaba's film, have a concentration gradient therein. Inaba discloses that the drug storing layers (2) or (3) may be produced by preparing a drug storing layer solution that is obtained by dissolving compounds and **stirring uniformly**, allowing it to stand and adequately deaerating it. Inaba, Col. 5: lines 35-60. In contrast, Applicant discloses creating a **concentration gradient** of at least one active ingredient **within a single layer cured film dosage** by applying a polar liquid carrier having the at least one active ingredient to **one surface** of a non-gelatin polymeric film and allowing the applied polar liquid carrier to associate and cure with the polymeric film. Application, ¶¶ [0046], [0048] and FIGS. 2-4. The concentration gradient within the film dosage is from a higher concentration of the active ingredient at a first side of the film dosage to a lower concentration of the active ingredient at a second side of the film dosage. *See* Application, e.g., FIG. 4. Accordingly, Inaba does not disclose or teach "a single layer cured film dosage having a concentration gradient within the film dosage, from a first concentration of the active ingredient at a first side of the film dosage, to a second concentration of the active ingredient at a second side of the film dosage, the second side being

opposite the first side, and the first concentration being greater than the second concentration," as recited in claim 16. Thus, because Inaba nowhere discloses at least these limitations of independent Claim 16, Inaba cannot anticipate Claim 16.

In view of the foregoing remarks, independent claim 16 is believed to be allowable over Inaba. Reconsideration and withdrawal of the § 102(b) rejection of independent claim 16 are respectfully requested.

Claims 26, 28, 43-52, 54, and 55 are dependent from independent claim 16 described above and, therefore, are believed to be allowable over Inaba for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, the individual consideration of each on its own merits is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 25 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2003/0183643 ("Fagen"). Claims 21, 22, and 37-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2004/0253434 ("Patel"). Claim 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent No. 6,783,768 ("Brown"). Claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of Fagen and further in view of U.S. Patent No. 7,112,361 ("Lynn"). Claims 32-34, and 37-39 have been cancelled, thereby rendering the rejection of these claims moot.

Claims 21, 22, 25, and 30 are dependent from independent claim 16 discussed above. None of the references applied in the § 103 rejections are seen to disclose or suggest anything to remedy the deficiencies of Inaba discussed above. Therefore, claims 21, 22, 25, and 30 are believed to be allowable over the applied references for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, however, the individual consideration of each on its own merits is respectfully requested.

Conclusion

In view of the foregoing comments, it is respectfully submitted that the present application is fully in condition for allowance, and that such action is earnestly solicited. If any questions remain, however, the Examiner is cordially invited to contact the undersigned attorney so that any such matters may be promptly resolved.

Applicant respectfully submits that the claims are in condition for allowance and have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicant's attorney, at the telephone number below, to resolve any such issues promptly.

Any remarks in support of patentability of one claim should not necessarily be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not necessarily be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully reserves the right to traverse any of the Examiner's rejections or assertions, even if not discussed herein. Applicant respectfully reserves the right to challenge later whether any of the cited references are prior art. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicant reserves the right to contest later whether a proper reason exists to combine prior art references.

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Respectfully submitted,

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